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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,770	12/29/2000	Kuber T. Sampath	00960-520PRO	7664

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BOSTON, MA 02110-2624

EXAMINER
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LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/581,770

Applicant(s)

SAMPATH ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 20-38 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicants' election with traverse of Group I, claims 6, 18, and 19 in Paper No. 12 is acknowledged. Applicants' election with traverse of the following species is also acknowledged: (a) OP-1; and (b) Smad 1.
2. Applicants' amendment in Paper No. 12 has been entered in full. Claims 1-19 have been canceled and claims 20-38 have been added.
3. Further Restriction of newly added claims 20-38 is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 20-27, 31, 33 (in part), 34 (in part), and 38 (in part), drawn to a method of for restoring cellular phenotype in a subject's cell affected by disease, damage, or age, comprising administering to the subject an effective amount of a morphogen to activate an intracellular pathway that induces intracellular formation of a Smad

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complex which induces expression of a phenotype-specific gene, thereby restoring the cellular phenotype in the subject's cell.

II. Claims 28-30, 32, 33 (in part), 34 (in part), and 38 (in part), drawn to a method for restoring cellular phenotype in a subject's cell affected by disease, damage, or age, comprising administering to the subject an effective amount of a morphogen to inhibit TGF- $\beta$  from promoting formation of scar tissue via fibrosis, thereby restoring the cellular phenotype in the subject's cell.

III. Claims 35-37, and 38 (in part), drawn to a method for inhibiting TGF- $\beta$  mediated fibrosis of tissue comprising contacting the tissue with an effective TGF- $\beta$  inhibiting amount of a morphogen, thereby inhibiting fibrosis of the tissue.

4. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Groups I-III are drawn to completely different methods each using different compositions, having completely different steps and biological outcomes. Invention Group I requires activation of an intracellular pathway (by a morphogen) that induces intracellular formation of a Smad complex; Invention Group II requires inhibiting TGF- $\beta$  (by a morphogen) from promoting formation of scar tissue via fibrosis; whereas invention Group III is drawn to method for inhibiting TGF- $\beta$  mediated fibrosis of tissue. Each method is unique and not required another. Thus, the methods are exclusive, which are not interchangeable and which require non-cohesive searches and considerations.

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5. The special technical feature in Groups I is a method of for restoring cellular phenotype in a subject's cell affected by disease, damage, or age, comprising administering to the subject an effective amount of a morphogen to activate an intracellular pathway that induces intracellular formation of a Smad complex which induces expression of a phenotype-specific gene, thereby restoring the cellular phenotype in the subject's cell; the special technical feature in Groups II is a method for restoring cellular phenotype in a subject's cell affected by disease, damage, or age, comprising administering to the subject an effective amount of a morphogen to inhibit TGF- $\beta$  from promoting formation of scar tissue via fibrosis, thereby restoring the cellular phenotype in the subject's cell; whereas the special technical feature in Groups III is a method for inhibiting TGF- $\beta$  mediated fibrosis of tissue comprising contacting the tissue with an effective TGF- $\beta$  inhibiting amount of a morphogen, thereby inhibiting fibrosis of the tissue.
6. Accordingly, Groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Thus, unity of invention is lacking and restriction is appropriate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
August 15, 2003

  
YVONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600